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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,781	01/02/2002	Christian Enggaard	P200000344 US	6319

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NOVO NORDISK PHARMACEUTICALS, INC
100 COLLEGE ROAD WEST
PRINCETON, NY 08540

EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,781	ENGGAARD, CHRISTIAN	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman et al., 5,104,380, in view of Petersen et al., 5,626,566.

Holman et al. disclose the invention substantially as claimed.

Specifically, as to claims 1, 19, 20, 23, 24 and 25, Holman discloses a housing (8), a drive member (2), a spring means (6), a dose setting assembly (1, 3, 7, 12 and 26) in the housing connected to the spring means, the dose setting assembly comprising a dose setting member (3) moveable in a first direction against the bias of the spring means, and wherein the dose setting member is moveable in a second direction to adjust the set dose, see column 3, lines 12-22, a latch means (9) to retain the apparatus against the bias of the spring means, and the latch means being releasable to cause the drive member to expel the set dose from the syringe from the fluid-filled reservoir when the dose –setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means, see column 3, lines 28-32. Holman teaches that the syringe cartridge can be used to inject medication such

as insulin, see column 2, line 54. Holman also discloses a dose setting assembly (1, 3, 7, 12 and 26).

However, Holman does not teach that the dose setting assembly is moveable in a second direction to adjust the set dose downward without moving the drive member.

Petersen also teaches a syringe cartridge that can be used to inject medication such as insulin (see column 3, lines 51-52.)

Petersen also teaches a dose setting assembly (18) the dose setting assembly comprising a dose setting member moveable in a first direction against the bias of the spring means, and wherein the dose setting member is moveable in a second direction to adjust the set dose, see column 5, lines 40-49, a latch means (24) to retain the apparatus against the bias of the spring means, and the latch means being releasable to cause the drive member to expel the set dose from the syringe, see column 5, lines 23-39.

As to claim 2, the dose setting assembly (18, 20 and 21) further comprises a coupling member (20) in displaceable engagement with the dose setting member (21), the spring means acting on the coupling member, the coupling member acting on the dose setting member, see column 5, lines 40-50.

As to claims 3 and 12, the dose setting member and the coupling member comprise mutually cooperating surfaces such that movement of the dose setting member results in straining of the spring means, see column 4, lines 63-67.

As to claim 4, one (20) of the dose setting member and the coupling member is rotationally mounted on the drive member, the other (21) being arranged in sliding, non-rotational engagement wit the drive member, see column 4, lines 40-47.

As to claim 5, the dose setting member (18 and 20) is rotationally mounted on a threaded portion of the drive member as claimed, see column 4, lines 38-42, and the spring means acting on the coupling member in a direction corresponding to the longitudinal axis of the drive member, see column 4, lines 53-64.

As to claims 6 and 13, the threaded connection is of the non-locking type, wherein the coupling allows the dose setting member to be rotated in either direction, as claimed, yet preventing the spring means to counter rotate the dose setting member, see column 4, line 58 – column 5, line 2.

As to claims 7 and 14, the coupling is between the cooperating surfaces of the dose setting member (20) and the coupling member (21) as claimed, see column 5, lines 40-46.

As to claims 8 and 9, the device further comprises a threaded member (22) with a first internal thread, the drive member (23) being a longitudinal drive member having an external thread corresponding to the first internal thread, as claimed.

As to claim 10, the dose setting member (18 and 20) comprises a second internal thread (22, see Figure 2), the dose setting member being rotationally mounted on the external thread of the piston drive member.

As to claim 11, the coupling member (20, 21) is arranged in sliding, non-rotational engagement with the piston drive member, the spring means acting on the coupling member as claimed, see column 4, lines 53-67.

As to claims 15, 16, 17 and 22, the coupling is provided by coupling parts having surfaces provided with sector shaped teeth having ramp shaped edges, as claimed, see column 4, lines 50-64.

As to claim 18, the coupling (20, 21) is a one-way ratchet mechanism.

As to claim 21, a second latch means is associated with the housing to retain the dose setting member in its coupled position, the second latch means being releasable to allow the dose setting member to disengage from the driving means.

Petersen teaches that the dosage setting assembly allows for cancellation of a set dose without the undesirable effect of loss of medication (see column 1, lines 40-43, and column 5, line 63 – column 6, line 4.)

It would have been obvious to one of ordinary skill in the art to substitute the dose setting assembly in the Petersen syringe for the dose setting assembly in the Holman syringe in order to allow for cancellation of a set dose without loss of medication. Or alternatively, it would have been obvious to substitute the spring and drive mechanism of the Holman syringe for the drive mechanism in the Petersen syringe, as a well known alternative mechanism for expelling medication in a syringe.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/23/04